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As argued by Defendants on appeal, Plaintiff's argument is wrong on several counts. First, in answering the complaint, Defendants specifically asserted the statute of limitations as an affirmative defense; second, Defendants expressly denied "any wrongdoing or liability" in the class action settlement; third, a settlement or an offer to settle cannot be used to prove liability under Fed. R. Evid. 408; and fourth, it has been found that a defendant does not waive a statute of limitations defense merely by engaging in settlement negotiations with a plaintiff. *See Thompson v. The Capital Police Bd.*, 120 F. Supp. 2d 78, 83-84 (D.D.C. 2000). We agree with Defendants in every respect and therefore conclude that Plaintiff's argument in this regard does nothing to change the conclusion that Plaintiff's claims are barred by the statute of limitations.

#### CONCLUSION

For the above-stated reasons, we **AFFIRM** the district court's order granting summary judgment to Defendants.

# RECOMMENDED FOR FULL-TEXT PUBLICATION Pursuant to Sixth Circuit Rule 206

ELECTRONIC CITATION: 2002 FED App. 0158P (6th Cir.) File Name: 02a0158p.06

# UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

SHERRY MICHALS,

Plaintiff-Appellant,

v.

BAXTER HEALTHCARE
CORPORATION and BAXTER
INTERNATIONAL, INC.,

Defendants-Appellees.

Appeal from the United States District Court for the Western District of Kentucky at Louisville. No. 93-00663—Charles R. Simpson III, District Judge.

Argued: November 29, 2001

Decided and Filed: May 6, 2002

Before: MERRITT, CLAY, and GILMAN, Circuit Judges.

#### COUNSEL

**ARGUED:** Curt L. Sitlinger, SITLINGER, McGLINCY, STEINER, THEILER & KAREM, Louisville, Kentucky, for Appellant. David L. Schrader, BROBECK, PHLEGER & HARRISON, Los Angeles, California, for Appellees. **ON BRIEF:** Curt L. Sitlinger, SITLINGER, McGLINCY,

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STEINER, THEILER & KAREM, Louisville, Kentucky, for Appellant. David L. Schrader, BROBECK, PHLEGER & HARRISON, Los Angeles, California, John L. Tate, Misty C. Schlatter, STITES & HARBISON, Louisville, Kentucky, for Appellees.

## **OPINION**

CLAY, Circuit Judge. Plaintiff, Sherry Michals, appeals from the district court's order granting summary judgment to Defendants Baxter Healthcare Corporation and Baxter International, Inc., on statute of limitations grounds, in this case wherein Plaintiff seeks damages for injuries she allegedly sustained as a result of breast implants manufactured by a corporation now owned by Defendants. This matter is in federal court based on diversity of citizenship, pursuant to 28 U.S.C. § 1332(a), and jurisdictional amount exceeding \$75,000. For the reasons set forth below, we **AFFIRM** the district court's order.

# **BACKGROUND Procedural History**

Plaintiff filed suit against Defendants on October 23, 1993, seeking damages for injuries she allegedly sustained as a result of silicone breast implants that she received in March of 1974, which were manufactured by Heyer-Schulte, a corporation now owned by Defendants. On June 8, 2000, Defendants filed a motion for summary judgment, claiming that Plaintiff's cause of action was time-barred under the one-year statute of limitations set forth in Kentucky Revised Statute 413.140. On August 23, 2000, the district court entered a memorandum opinion granting Defendants' motion for summary judgment, and on August 29, 2000, the district court entered its corresponding order dismissing Plaintiff's suit. This timely appeal ensued.

# B. Plaintiff's Argument that the Language of the Opt-Out Provision Tolled the Statute of Limitations

Plaintiff contends that pursuant to the language of the optout provision, the statute of limitations was tolled for six months from the time the claims office received Plaintiff's opt-out form. As stated, the provision of the opt-out form upon which Plaintiff relies states as follows:

NOTE: The running of any applicable statutes of limitation or repose with respect to the claims against person and entities named as released parties in the original global settlement – except Dow Corning, Mentor, and Bioplasty – will resume 6 months after the date this form is received in the claims office.

(J.A. at 80.) According to the express language of this provision, the applicable statute of limitations is only tolled for six months to the extent that the statute has not already run. In other words, by stating that the applicable statute will resume six months after the opt-out form is received in the claims office, the provision necessarily assumes that the statute has not already run. Because the statute of limitations had long expired by the time Plaintiff sent the opt-out form to the claims office in October of 1996, this provision does not apply to save Plaintiff's claims.

# C. Plaintiff's Contention that Defendants Waived the Right to Assert the Statute of Limitations as an Affirmative Defense

Plaintiff argues that as evidenced by the Notification of Status received by Plaintiff on October 2, 1996, Defendants waived their right to assert the statute of limitations as a defense. Plaintiff contends that by including Plaintiff in settlement negotiations and extending a settlement negotiation offer to her, Defendants waived their reliance on the statute of limitations. Plaintiff fails to cite any authority in support of this contention, and we find the contention without merit in any event.

Healthcare Corp., et al.

One could argue that although Plaintiff was aware of legally cognizable injury from the implants in 1993 when she filed her claim based on theories such as negligence, there is nothing in the 1993 claim to indicate that she knew of a legally cognizable injury based upon a defective product until 1996 when she received the Notification of Status letter. Accordingly, at least to her 1996 products liability action, the argument goes that the statute did not begin to run until October of 1996, thereby making the 1996 products liability action timely.

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This argument is quickly loses its force upon review of Plaintiff's 1993 complaint. There, Plaintiff begins by stating as follows:

#### **COMPLAINT AND ADOPTION BY REFERENCE**

1. Plaintiff, Sherry Michals, a citizen and resident of Kentucky, states her claims against the defendants indicated below as follows and incorporates by reference the relevant portions of the Master Complaint on file in the case styled In re: Silicone Gel Breast Implant Products Liability Litigation (MDL-926), now pending in the United States District Court for the Northern District of Alabama, before the Honorable Sam C. Pointer, Civil Action File No. CV-92-P-10000-S.

(J.A. at 13 (emphasis in original).) Therefore, Plaintiff's contention that she could not reasonably be considered to have been aware of her products liability claim against Defendant until 1996 when she received the Notification of Status letter is disingenuous, at best. Obviously, Plaintiff not only was aware that the silicone implants were allegedly defective in 1993 when she filed her complaint, but in fact incorporated allegations of product defect into the 1993 complaint, as the first paragraph indicates.

### **Facts**

In March of 1974, Dr. Leonard Weiner surgically implanted Heyer-Schulte silicone breast implants in Plaintiff. Plaintiff elected to have this surgery because her breasts had become quite enlarged when she was pregnant with her daughter, and her breasts remained large postpartum due to engorgement which caused a degradation of the contour and support of her breasts. In the two months following the surgery, Plaintiff saw Dr. Weiner three times for follow-up visits. Plaintiff did not see a physician again regarding her breast implants until March of 1976, when she saw Dr. Norman Cole. Plaintiff claims that she went to see Dr. Cole because her "breasts hurt and they were still hard and still red and they were immobile and [she] was getting red rashes across them." In an effort to soften Plaintiff's breasts, Dr. Cole performed a closed capsulotomy on Plaintiff that involved physical manipulation of her breasts in order to break the fibrous capsules. Although the capsulotomy was effective at first, Plaintiff's breasts eventually returned to the hardened state. At that point, Dr. Cole recommended that Plaintiff have the implants removed and replaced.

In March of 1977, Plaintiff underwent surgery to have the Heyer-Schulte implants replaced with Dow Corning implants. In January of 1979, the left implant was replaced with another Dow Corning implant; and, in September of 1992, Plaintiff had both implants removed and replaced with a pair of silicone implants manufactured by Mentor. During the 1992 surgery, the operating physician discovered that the previous silicone Dow implants had ruptured, and that silicone had escaped into Plaintiff's breast tissue. In March of 1993, Plaintiff underwent breast surgery again, at which time her Mentor implants were replaced with another set of Mentor implants. Finally, in March of 1994, Plaintiff had the Mentor silicone implants replaced with saline implants manufactured by McGhan.

Plaintiff claims that as a result of the silicone implants rupturing, she now experiences migraine headaches; arthralgia; symptoms of lupus, although tests come back negative for this disease; arthritis; autoimmune thyroiditis; irritable bowel syndrome; rashes; muscles and joint pain; leg swelling; sensitivity to the sun; and loss of hair. Plaintiff claims that during the time that she had the Heyer-Schulte implants, she experienced migraine headaches, rashes, and possibly leg swelling.

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Plaintiff had filed the instant suit against Defendants and Dow Corning on October 22, 1993, claiming the breast implants manufactured by Defendants and Dow Corning were the proximate cause of injuries from which she suffered, and she sought damages for these injuries under twenty-eight theories including strict liability, negligence, failure to warn, and breach of express and implied warranties.

In October of 1996. Plaintiff received a Notification of Status letter regarding the settlement of a class action lawsuit filed against Defendants. Plaintiff opted out of the settlement class by signing the opt-out form so indicating on October 17, 1996. The opt-out form contained the following language:

NOTE: The running of any applicable statutes of limitation or repose with respect to the claims against person and entities named as released parties in the original global settlement – except Dow Corning, Mentor, and Bioplasty – will resume 6 months after the date this form is received in the claims office.

(J.A. at 80.) Plaintiff's signed opt-out form was mailed to the claims office on November 21, 1996. Plaintiff added a products liability claim to her October 22, 1993 complaint on October 23, 1996.

#### DISCUSSION

This Court reviews a district court's order on a motion for summary judgment de novo. See Miller v. Am. Heavy Lifting,

In the matter at hand, Plaintiff claims that based upon Wiseman, the point in time that she became aware of "the invasion of a legally protected interest" was in 1996 when she received the Notification of Status letter regarding the settlement of the class action lawsuit. Plaintiff argues that, as in Wiseman, although she may have been aware that the Heyer-Schulte implants had caused her harm – or as Plaintiff specifically characterizes it, caused her dissatisfaction and discomfort – in March of 1977, leading her to have the implants removed and replaced, she was not aware that she had an injury for purposes of the discovery rule until she became aware that the product was defective.

Plaintiff was aware of physical injuries that she sustained such as breast hardness, immobility, redness, and a rash in 1977 when she had the implants removed. Plaintiff specifically attributed these injuries to the Heyer-Schulte implants in particular, as evidenced by her decision to have the Heyer-Schulte implants replaced with Dow Corning implants. Therefore, unlike the Plaintiff in Wiseman who experienced pain but was unaware that the pain was attributable to the the uterine probe left in her body, Plaintiff in the matter at hand was fully aware that the harm she experienced was attributable to the Heyer-Schulte implants, as evidenced by her decision to have them removed and replaced at the advice of her physician in order to ameliorate the injury. See Wiseman, 37 S.W.2d at 712-13. In addition, Plaintiff's argument in the district court, attributing the problems associated with her breasts due to a foreign substance in her body and not specifically to the Heyer-Schulte implants, flies in the face of her decision to have the implants replaced with implants manufactured by Dow Corning. Hence, the date of accrual for purposes of the statute of limitations is March 9, 1977, at the latest, and the statutory period ran on March 9, 1978, thereby rendering Plaintiff's 1993 complaint and the allegations made therein untimely. See id.

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"the invasion of any legally protected interest of another[,]" thus triggering the running of the statutory clock. *Id.* (quoting The Restatement (Second) of Torts § 7, comment (1965)). To illustrate, "[h]arm could result from a successful operation where a communicated, calculated risk simply turns out poorly for the patient, although the medical treatment met the highest medical standards[;]" however, despite the existence of the "harm," there would be no injury in such a case. *Id.* (quoting *Hall v. Musgrave*, 517 F.2d 1163, 1168 (6th Cir. 1975) (Celebrezze, J., dissenting)).

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Applying the discovery rule to the facts in Wiseman, the Kentucky Supreme Court found that the plaintiff's cause of action in that case did not accrue until "the fact of her injury became objectively ascertainable." See 37 S.W.2d at 713. In this regard, the court found that "while [the plaintiff] may have suspected that something went wrong during the surgery, that in and of itself was insufficient to accrue a cause of action." Id. The Wiseman court went on to hold that

[a] legally recognizable injury does not exist until the plaintiff discovers the defendant's wrongful conduct. Because Appellant's injury was not readily apparent until the discovery of the piece of uterine probe, she was unaware that she had a viable claim for medical malpractice. A mere suspicion of injury due to medically unexplainable pain following an invasive surgery does not equate to discovery of medical negligence. . . . In order to trigger the statute of limitations, a plaintiff must discover the injury – the invasion of a legally protected interest. Appellant filed her medical malpractice complaint within one year from the date she became aware she had been injured as a result of Dr. Ulfe's negligence. As such, the trial court erred in granting summary judgment.

231 F.3d 242, 246-47 (6th Cir. 2000). Likewise, this Court reviews a district court's determination that a complaint was filed outside the relevant statute of limitations de novo. See

Defendants argue that the district court properly dismissed Plaintiff's claims as time-barred inasmuch as Kentucky's oneyear statute of limitations bars Plaintiff's personal injury action. Defendants contend that Plaintiff's claims began to accrue on March 9, 1977, when she had the Heyer-Schulte implants removed and replaced with Dow Corning implants, and because Plaintiff did not file suit until 1993 or 1996, her claims with respect to Defendants were well beyond the onevear limit.

Defendants further contend that Plaintiff's claims are not saved by the application of Kentucky's discovery rule. According to Defendants, under that rule, the statute of limitations still began to run on March 9, 1977, because that was the point at which Plaintiff should have reasonably known that the Heyer-Schulte implants caused her injury, even if she was not aware of the full extent of the injuries at that time. In other words, Defendants do not claim that the statute of limitations began to accrue immediately after she had the Heyer-Schulte implants on March 4, 1974; rather, Defendants argue that the point in time that it could be said that Plaintiff reasonably knew or "discovered" that the Heyer-Schulte implants caused her injuries was March 9, 1977, the date upon which she had the implants removed and replaced at the advice of her physician. In support of this contention, Defendants rely upon Plaintiff's testimony that she went to see Dr. Cole in March of 1976 because her "breasts hurt and they were still hard and still red and they were immobile and [she] was getting red rashes across them[,]" (J.A. at 231), and after Dr. Cole tried to correct the problems of which Plaintiff complained by performing capsulotomies, Plaintiff finally underwent surgery to have the Heyer-Schulte removed and replaced with Dow Corning implants on March 9, 1977. Therefore, according to Defendants, by March 9, 1977,

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Plaintiff knew of the injuries allegedly caused by the Heyer-Schulte implants – even if she was not fully aware of the extent of her injuries – such that Plaintiff's date of accrual for purposes of the statute of limitations was March 9, 1977, thereby making March 9, 1978 the last day of the statutory period.

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Plaintiff responds by arguing that the date she reasonably became aware that her complaints were due to a defective product was in October of 1996 when she received the Notification of Status letter regarding the settlement of a class action lawsuit filed against Defendants. Plaintiff further argues that because the opt-out form provided that the applicable statute of limitations would "resume 6 months after the date [the] form was received in the claims office[,]" because Plaintiff's form was received in the claims office on November 21, 1996, and because she filed her products liability claim on October 23, 1996, she was well within the statue of limitations. Finally, Plaintiff argues that Defendants should not be allowed to assert the statute of limitations affirmative defense inasmuch as Defendants entered into the class action settlement thereby constituting an admission of fault; and, by opting out of the settlement agreement, the statute of limitations began a new. We disagree with Plaintiff's arguments.

# A. Date Plaintiff's Claim Against Defendants Accrued for Injuries that She Allegedly Received as a Result of the Heyer-Schulte Implants

Under Kentucky law, a personal injury action must be commenced within one year after the cause of action accrued. See KY. REV. STAT. ANN. § 413.140(1)(a) (Banks-Baldwin 1991). Generally, this means that the plaintiff must file suit within one year of the alleged injury. See Caudill v. Arnett, 481 S.W.2d 668, 669 (Ky. 1972). However, Kentucky law also provides for an exception to this general rule through what is known as the "discovery rule." Recently, the Kentucky Supreme Court opined about this rule as follows:

The discovery rule, a means by which to identify the "accrual" of a cause of action when an injury is not readily ascertainable or discoverable, was first enunciated in Tomlinson v. Siehl, 459 S.W.2d 166 (Ky. 1970), and later refined in *Hackworth v. Hart*, 474 S.W.2d 377 (Ky. 1971): "[T]he statute begins to run on the date of discovery of the injury, or from the date it should, in the exercise of ordinary care and diligence, have been discovered." Id. This rule entails knowledge that a plaintiff has a basis for a claim before the statute of limitations begins to run. The knowledge necessary to trigger the statute is two-pronged; one must know: (1) he has been wronged; and, (2) by whom the wrong has been committed. Drake v. B.F. Goodrich Co., 782 F.2d 638, 641 (6th Cir. 1986). See also Hazel v. General Motors Corp., 863 F. Supp. 435, 438 (W.D. Ky. 1994) ("Under the 'discovery rule,' a cause of action will not accrue until the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, not only that he has been injured but also that his injury may have been caused by the defendant's conduct.").

Wiseman v. Alliant Hosps., Inc., 37 S.W.2d 709, 712 (Ky. 2001).

The Kentucky court explained that the discovery rule is dependant upon ascertaining the date on which the plaintiff had "actual or constructive knowledge of the injury which triggers the running of the statute of limitations." See Wiseman, 37 S.W.2d at 712. The court distinguished between the time the plaintiff discovered "harm" and the time the plaintiff discovered "injury" as being critical to the application of the discovery rule. See id. The former, discovered harm, does not trigger the running of the statute of limitations inasmuch as "harm" is defined by the Restatement as "the existence of loss or detriment in fact of any kind to a person resulting from any cause." Id. (quoting The Restatement (Second) of Torts § 7, comment (1965)). The court noted that "injury," on the other hand, is defined as